



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

FEB 28 2005

Anthony C. Celeste
President
AAC Consulting Group
7361 Calhoun Place
Suite 500
Rockville, MD 20855-2765

Re: Docket No. 2004P-0379/CP1

Dear Mr. Celeste:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition dated August 25, 2004. Your petition requests that FDA determine whether Penthrane (methoxyflurane) Inhalation Liquid 99.9% was withdrawn from sale for reasons of safety or effectiveness.

FDA has yet to reach a decision on your petition because of the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

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